

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Narasin and Bacitracin Zinc

**AGENCY:** Food and Drug Administration, HHS.

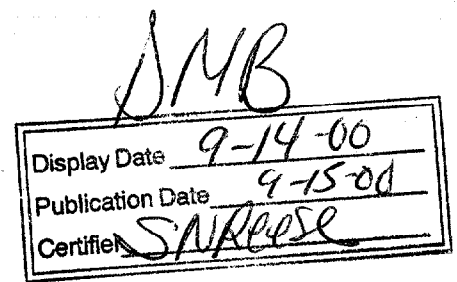
**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Roche Vitamins, Inc. The NADA provides for use of approved narasin and bacitracin zinc Type A medicated articles to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in broiler chickens.

**DATES:** This rule is effective [insert date of publication in the **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, filed NADA 140-865 that provides for use of Monteban® (36, 45, 54, 72, or 90 grams per pound (g/lb) narasin activity) and Baciferm® (10, 25, 40, or 50 g/lb bacitracin activity as bacitracin zinc) Type A medicated articles to make two-way combination Type C medicated feeds for broiler chickens. The combination Type C medicated feeds contain 54 to 72 g/ton narasin and 4 to 50 g/ton bacitracin zinc and are used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of August 7, 2000, and the regulations are amended in §§ 558.78 and 558.363 (21 CFR 558.78 and



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558.363) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 558.78 is also amended editorially to consolidate the cross-references for approved combinations in paragraph (d)(3) and list them in alphabetical order.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.78 is amended by revising paragraph (d)(3) to read as follows:

**§ 558.78 Bacitracin zinc.**

\* \* \* \*

(d) \* \* \*

(3) It may be used as approved in combination with:

(i) Amprolium alone and with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone and with roxarsone as in § 558.58.

(iii) Carbarsone as in § 558.120.

(iv) Clopidol alone and with roxarsone as in § 558.175.

(v) Decoquate alone and with roxarsone as in § 558.195.

(vi) Hygromycin B alone and with penicillin as in § 558.274.

(vii) Lasalocid sodium alone or with roxarsone as in § 558.311.

(viii) Monensin alone and with roxarsone as in § 558.355.

(ix) Naracin as in § 558.363.

(x) Robenidine as in § 558.515.

(xi) Salinomycin alone and with roxarsone as in § 558.550.

(xii) Zoalene alone and with arsanilic acid or roxarsone as in § 558.680.

3. Section 558.363 is amended by adding paragraphs (a)(7) and (d)(1)(x) to read as follows:

**§ 558.363 Narasin.**

(a) \* \* \*

(7) To 063238: 36, 45, 54, 72, or 90 grams per pound, with 10, 25, 40, or 50 grams per pound bacitracin zinc, paragraph (d)(1)(x) of this section.

\* \* \* \*

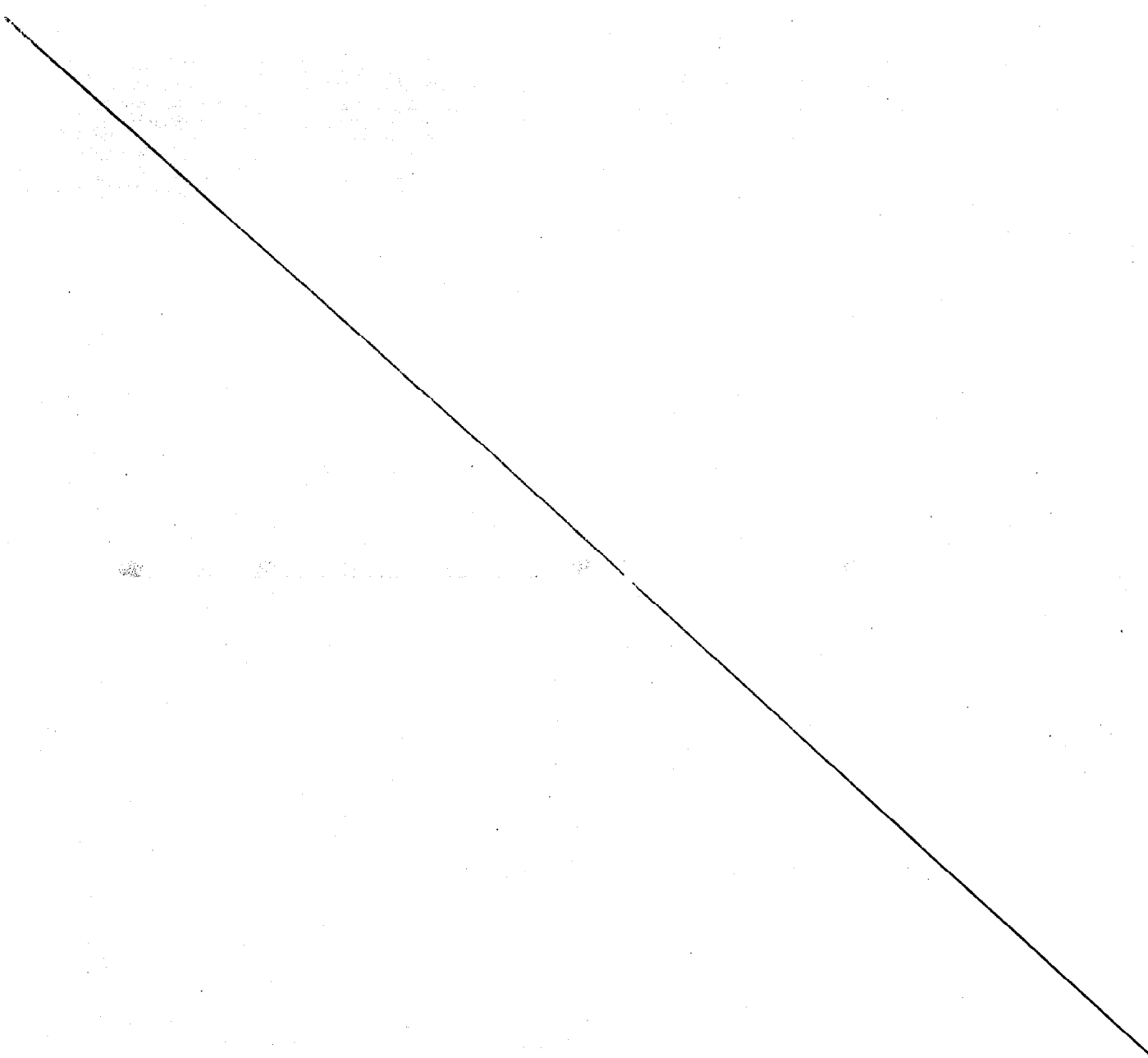
(d) \* \* \*

(1) \* \* \*

(x) *Amount per ton.* Narasin, 54 to 72 grams and bacitracin zinc, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of



narasin by these species has been fatal. Narasin as provided by 000986, bacitracin zinc by 063238 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: 8/5/00  
August 5, 2000

37 S. F.  
Stephen F. Sundlof  
Director  
Center for Veterinary Medicine.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Segeth N. Rose